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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,548	06/26/2007	Christof Dutoit	10139/08702	4856

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EXAMINER	
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ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
01/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,548	DUTOIT ET AL.	
	Examiner	Art Unit	
	Randall J. Nelson	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/26/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/01/2006 and 01/14/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: page 4, lines 29-30, the phrase “thread lead G” is unclear. Appropriate correction is required.

Claim Objections

2. **Claim 29** is objected to because of the following informalities: the phrase “the axial connection element preventing relative securing the anchoring element to the shaft” is unclear. For examination purposes, the examiner is interpreting this phrase to mean “the axial connection element permitting motion between the anchoring element and the shaft”. Appropriate correction is required.

3. **Claim 39** is objected to because of the following informalities: the applicant indicates **Claim 39** as being dependent from cancelled claim (**Claim 1)**. For examination purposes, the examiner is interpreting **Claim 39** as being dependent from **Claim 28**. Appropriate correction is required.

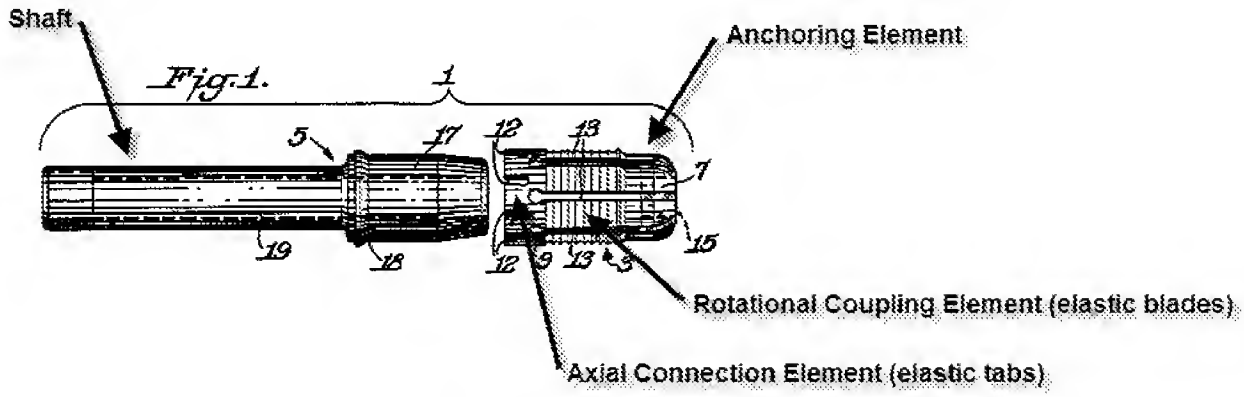
4. **Claims 48-49** are objected to because of the following informalities: the phrases, "pitch of G" and "the pitch G", are unclear. For examination purposes, the examiner is interpreting these phrases to mean “pitch”. Appropriate correction is required.

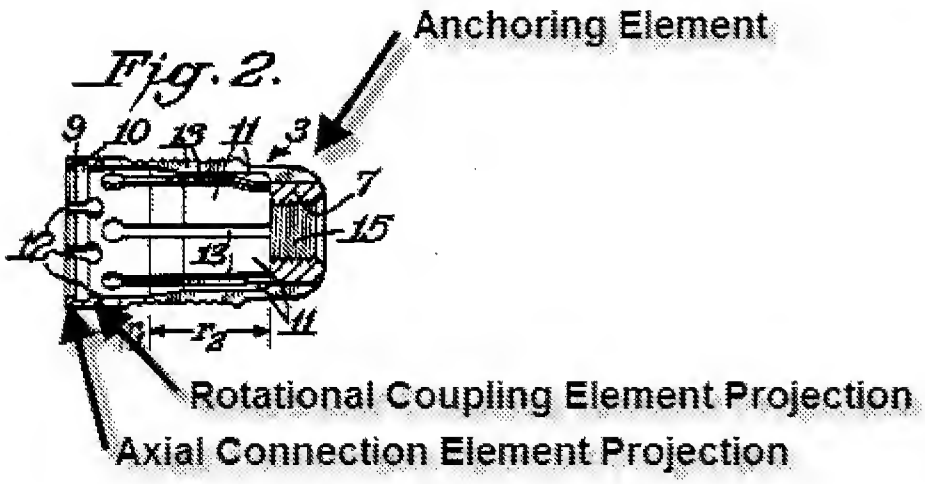
Claim Rejections - 35 USC § 102

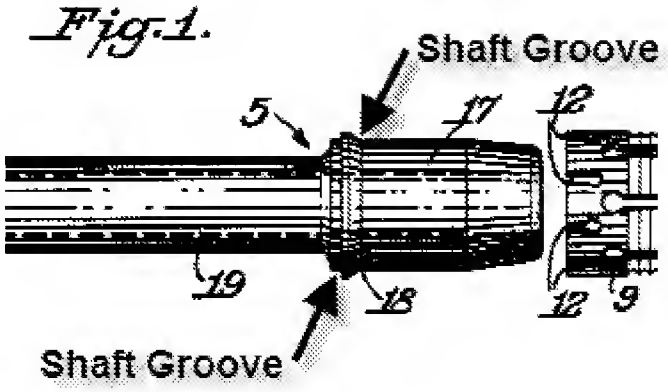
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 28-36, 39-41, 44-47, and 52** are rejected under 35 U.S.C. 102(b) as being anticipated by Chapman et al. (US 5,772,662).







7. Regarding **Claim 28**, Chapman et al. disclose a bone fixation implant comprising a longitudinal shaft (see above figures) having a first end, a second end, and a central longitudinal axis. Included, is an anchoring element (see above figures) at the first end of the shaft (see above figures) wherein the anchoring element (see above figures) is configured and dimensioned for engaging bone (col. 12, lines 30-32). A rotational coupling element (see above figures) is provided at an interface between the anchoring element (see above figures) and the shaft (see above figures). The coupling element (see above figures) is configured and dimensioned to permit free rotation of the anchoring element (see above figures) relative to the shaft (see above figures) about the central longitudinal axis when in a first position (shaft partially inserted into anchoring element) and rotationally lock the anchoring element (see above figures) to the shaft (see above figures) when in a second position (shaft fully inserted into anchoring element).

8. Regarding **Claim 29**, Chapman et al. disclose an implant comprising an axial connection element (see above figures) disposed at an interface between the anchoring element (see above figures) and the shaft (see above figures). The axial connection element (see above figures) permits motion between the anchoring element (see above figures) and the shaft (see above figures) along the central longitudinal axis.

9. Regarding **Claim 30**, Chapman et al. disclose an implant wherein the axial connection element (see above figures) and the rotational coupling element (see above figures) are separate structures.

10. Regarding **Claim 31**, Chapman et al. disclose a bone fixation implant wherein the anchoring element (see above figures) is detachably connected to the shaft (see above figures).

11. Regarding **Claim 32**, Chapman et al. disclose a bone fixation implant wherein the axial connection element (see above figures) includes a plurality of spaced-apart, elastic tabs (see above figures) (col. 12, lines 36-38).

12. Regarding **Claim 33**, Chapman et al. disclose a bone fixation implant wherein the elastic tabs (see above figures) include projections (see above figures) that engage a complementary, circular groove (see above figures indicating the left shaft groove) concentric with the longitudinal axis.

13. Regarding **Claim 34**, Chapman et al. disclose a bone fixation implant wherein the elastic tabs (see above figures) are disposed on the anchoring element (see above figures) and the groove (see above figures) is disposed at the shaft (see above figures).

14. Regarding **Claim 35**, Chapman et al. disclose a bone fixation implant wherein the projections (see above figures) have a convex shape (see above figures).

15. Regarding **Claim 36**, Chapman et al. disclose a bone fixation implant wherein the groove (see above figures) has a V-shaped cross section (see above figures).

16. Regarding **Claim 39**, Chapman et al. disclose a bone fixation implant wherein the rotational coupling element (see above figures) rotationally locks the shaft (see above figures) and the anchoring element (see above figures) through a frictional connection (shaft fully inserted into anchoring element).

17. Regarding **Claim 40**, Chapman et al. disclose a bone fixation implant wherein the rotational coupling element (see above figures) includes a hollow, conical volume (see above figures) disposed coaxially with the longitudinal axis at an interface between the shaft (see above figures) and the anchoring element (see above figures). Also, disclosed is a conical wedge (note the conical wedge near the right end of the shaft) configured and dimensioned for axial movement within the conical volume (see above figures) wherein movement of the conical wedge (note the conical wedge near the right end of the shaft) in a first direction within the conical volume (see above figures) frictionally locks the shaft relative to the anchoring element (see above figures) (shaft fully inserted into anchoring element).

18. Regarding **Claim 41**, Chapman et al. disclose a bone fixation element wherein the hollow, conical volume (see above figures) includes a first conical volume provided in the shaft (see above figures) and a second corresponding conical volume provided in the anchoring element (see above figures) (note the hollow conical volume or space of the anchoring element and the corresponding conical volume or mass of the shaft).

19. Regarding **Claim 44**, Chapman et al. disclose a bone fixation implant wherein the rotational coupling element (see above figures) rotationally locks the shaft (see above figures) and the anchoring element (see above figures) through a positive connection (positive or frictional connection with shaft fully inserted into anchoring element).

20. Regarding **Claim 45**, Chapman et al. disclose a bone fixation implant wherein the rotational coupling element (see above figures) includes a first denticulation (see above figures) at the anchoring element (see above figures) configured and dimensioned to

engage a second denticulation (see above figures indicating the right shaft groove) at the shaft (see above figures).

21. Regarding **Claim 46**, Chapman et al. disclose a bone fixation implant wherein the second denticulation (see above figures indicating the right shaft groove) is axially-displaceable for engagement with the first denticulation (see above figures).

22. Regarding **Claim 47**, Chapman et al. disclose a bone fixation implant wherein the second denticulation (see above figures indicating the right shaft groove) is axially displaced by means of a screw (col. 12, lines 5-9 indicates the movement of the shaft via a threaded tool).

23. Regarding **Claim 52**, Chapman et al. disclose a method for repairing a bone fracture comprising inserting a bone fixation implant into a fractured bone. The bone fixation implant includes a shaft (see above figures) having a first end, a second end, and a central longitudinal axis. Included, is an anchoring element (see above figures) at the first end of the shaft (see above figures). The anchoring element (see above figures) is configured and dimensioned for engaging the bone (col. 12, lines 30-32). A rotational coupling element (see above figures) is configured to permit free rotation of the anchoring element (see above figures) with respect to the shaft (see above figures) about the central longitudinal axis when in a first position (shaft partially inserted into anchoring element) and rotationally lock the anchoring element (see above figures) to the shaft (see above figures) when in a second position (shaft fully inserted into anchoring element). A method further comprises inserting a bone plate (45, fig. 18) having a sleeve (53, fig. 18) keyed to mate with the shaft (see above figures) of the

bone fixation implant over the shaft (see above figures) of the bone fixation implant, aligning the bone plate (45, fig. 18) with the fractured bone, and moving the rotational coupling element (see above figures) into the second position (shaft fully inserted into anchoring element) to rotationally lock the anchoring element (see above figures) to the shaft (see above figures).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

26. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

27. **Claims 37-38 and 48-49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. (US 5,772,662) in view of Bramlet (US 5,827,285).

28. Regarding **Claim 37**, Chapman et al. disclose a bone fixation implant comprising an axial connection element (see above figures) and a complementary circular groove (see above figures indicating the left shaft groove) concentric with the longitudinal axis, but fail to disclose a pin fixed transversely to the longitudinal axis wherein the pin engages a complementary circular groove.

However, Bramlet teaches a pin (152, fig. 56) fixed transversely to the longitudinal axis wherein the pin (152, fig. 56) engages a complementary circular groove (26, fig. 56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Chapman et al. with a pin fixed transversely to the longitudinal axis wherein the pin engages a complementary circular groove, as taught by Bramlet, since doing so would provide a more secure means of axial connection.

29. Regarding **Claim 38**, Chapman et al. disclose a bone fixation implant comprising an axial connection element (see above figures) and an annular groove at the shaft (see above figures indicating the left shaft groove) which is concentric with the longitudinal axis, but fail to disclose a retaining ring that engages a first annular groove at the shaft and a second annular groove at the anchoring element wherein the first and second annular grooves are concentric with the longitudinal axis.

However, Bramlet teaches a retaining ring (252, fig. 60) that engages a first annular groove at the shaft (26, fig. 60) and a second annular groove at the anchoring element (see fig. 60) wherein the first (26, fig. 60) and second (see fig. 60) annular grooves are concentric with the longitudinal axis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Chapman et al. with a retaining ring that engages a first annular groove at the shaft and a second annular groove at the anchoring element wherein the first and second annular grooves are concentric with the longitudinal axis, as taught by Bramlet, since doing so would provide a more secure means of axial connection.

30. Regarding **Claim 48**, Chapman et al. disclose a bone fixation implant wherein the anchoring element (see above figures) includes a plurality of blades having a pitch (see above figures), but fail to disclose the blades being helical.

However, Bramlet teaches helical blades (see fig. 58).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Chapman et al. with helical blades, as taught by Bramlet, since doing so would provide an improved means of securing the anchoring element to bone.

31. Regarding **Claim 49**, Chapman et al. disclose a bone fixation implant with a pitch (see above figures), but fail to disclose a pitch greater than 50 mm.

However, Bramlet teaches a pitch greater than 50 mm (col. 15, lines 12-16 describe a “relatively course pitch").

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Chapman et al. with a pitch greater than 50 mm, as taught by Bramlet, since doing so would provide for a greater substantive holding force when the bone fixation element is threadably secured within a bone fragment.

32. **Claims 42-43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. (US 5,772,662) in view of Steiner et al. (US 6,221,107 B1).

33. Regarding **Claim 42**, Chapman et al. disclose a bone fixation implant wherein the rotational coupling means (see above figures) includes a plurality of radially elastic blades (see above figures) disposed at the anchoring element (see above figures) configured and dimensioned for insertion within a central borehole (col. 12, lines 30-32) at the first end of the shaft (see above figures). Also, included is a conical wedge (note the conical wedge near the right end of the shaft) configured and dimensioned to press the elastic blades (see above figures) against an inner wall of the central borehole to rotationally lock the shaft (see above figures) to the anchoring element (see above figures) (shaft fully inserted into anchoring element). Chapman et al. fail to disclose a conical locking screw.

However, Steiner et al. teach a conical locking screw (242, fig. 8; col. 8, lines 45-56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Chapman et al. with a conical locking screw, as taught by Steiner et al. since doing so would provide a more secure engagement between the conical wedge and the rotational coupling element. An improved

engagement would enhance the ability to rotationally lock the shaft to the anchoring element.

34. Regarding **Claim 43**, Chapman et al. disclose a bone fixation element wherein the radially elastic blades (see above figures) include projections (see above figures) configured and dimensioned to engage a complementary circular groove (see above figures indicating the right shaft groove) at the shaft (see above figures) concentric with the longitudinal axis.

35. **Claims 50 and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. (US 5,772,662) in view of Callender (US 3,374,786).

36. Regarding **Claim 50**, Chapman et al. disclose a bone fixation implant comprising a shaft (see above figures), but fail to disclose a shaft having a non-circular cross-section.

However, Callender teaches a shaft (28, fig. 2) having a non-circular cross-section. The shaft (28, fig. 2) has a non-circular cross-section because of a "groove" (50, fig. 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Chapman et al. with a shaft having a non-circular cross-section, as taught by Callender, since doing so would provide a physical and visual guide to aid in the placement of the bone fixation implant.

37. Regarding **Claim 51**, Chapman et al. disclose a bone fixation system comprising a bone plate (45, fig. 18) configured and dimensioned for attachment to a femur. The bone plate (45, fig. 18) includes an angular sleeve (53, fig. 18) adapted to receive a

bone fixation implant. The bone fixation implant is configured and dimensioned for use with the bone plate (45, fig. 18). The bone fixation implant includes a shaft (see above figures) having a first end, a second end, and a central longitudinal axis. Also, included is an anchoring element (see above figures) at the first end of the shaft (see above figures). The anchoring element (see above figures) has a plurality of blades (see above figures) for engaging bone (col. 12, lines 30-32). An axial connection element (see above figures) is disposed at an interface between the anchoring element (see above figures) and the shaft (see above figures). The axial connection element (see above figures) prevents axial movement of the anchoring element (see above figures) relative to the shaft (see above figures) along the central longitudinal axis. A rotational coupling element (see above figures) is disposed at an interface between the anchoring element (see above figures) and the shaft (see above figures). The coupling element (see above figures) is configured and dimensioned to permit free rotation of the anchoring element (see above figures) with respect to the shaft (see above figures) about the central longitudinal axis when in a first position (shaft partially inserted into anchoring element) and rotationally lock the anchoring element (see above figures) to the shaft (see above figures) when in a second position (shaft fully inserted into anchoring element). Chapman et al. fail to disclose an angular sleeve with a non-circular cross-section and an anchoring element having a plurality of helically-twisted blades.

However, Callender teaches an angular sleeve (26, fig. 3) with a non-circular cross-section (56, fig. 5; col. 3, lines 12-14; the “key” formed on the sleeve provides a

sleeve with a non-circular cross-section) and an anchoring element (30, fig. 2) having a plurality of helically-twisted blades (see fig. 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Chapman et al. with an angular sleeve with a non-circular cross-section, as taught by Callender, since doing so would provide a physical and visual guide to aid in the placement of the bone fixation implant. Also, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Chapman et al. with an anchoring element having a plurality of helically-twisted blades, as taught by Callender, since doing so would provide an improved means of securing the anchoring element to bone.

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited art of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall J. Nelson whose telephone number is (571)270-1661. The examiner can normally be reached on M-F 7:30-5:00 E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Randall J. Nelson/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733